Docket No.: 12013/48803

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT : Richard S. KUSLEIKA

SERIAL NO. : 10/825,309

FILED : April 16, 2004

FOR : CATHETER FOR TISSUE DILATION AND DRUG DELIVERY

GROUP ART UNIT : 3763 Confirmation No. 7747

EXAMINER : Quynh-Nhu Hoang Vu

M.S. Amendment
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PRE-APPEAL BRIEF REQUEST FOR REVIEW

SIR:

The Applicant respectfully requests pre-appeal brief review of the rejections in this application. Claims 16-24, 38 and 39 are pending and stand rejected under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 4,994,033 to Shockey, *et al.* ("Shockey") in view of U.S. Patent No. 5,447,497 to Sogard, *et al.* ("Sogard").

Applicant's Invention

Claim 16, the only pending independent claim, recites (underlining for emphasis supplied):

> 16. A process for treating tissue at a treatment site within a body lumen, comprising:
>
> providing an elongate flexible catheter having a flexible treatment sheath mounted to a distal end region of the catheter and a dilatation balloon within the flexible treatment sheath, wherein the flexible treatment sheath is formed of an elastic material and the dilatation balloon is formed of a substantially inelastic material;
>
> intraluminally advancing the elongate flexible catheter until the flexible treatment sheath is adjacent a predetermined treatment site;
>
> while maintaining the dilatation balloon in an unexpanded condition, supplying a treatment fluid under pressure to a compartment formed by the treatment sheath, to elastically expand the treatment sheath radially into a substantially conforming contact with the surrounding tissue at the treatment site,

cause the treatment fluid to pass through the treatment sheath from the compartment to the surrounding tissue, and maintain the treatment sheath expanded into said contact; and

while maintaining the treatment sheath in said substantially conforming contact with the surrounding tissue at the treatment site, radially expanding the dilatation balloon within the compartment, whereby the dilatation balloon acts radially upon the surrounding tissue through the treatment sheath to effect a dilatation of the surrounding tissue.

An example embodiment is illustrated in Figures 5 and 6, reproduced below:

Fig.-5

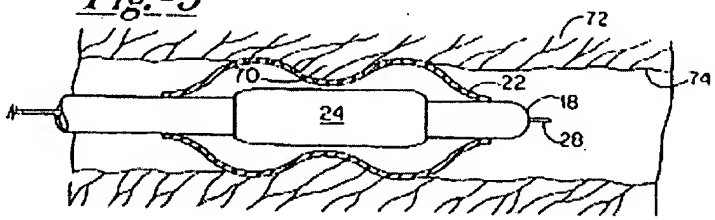
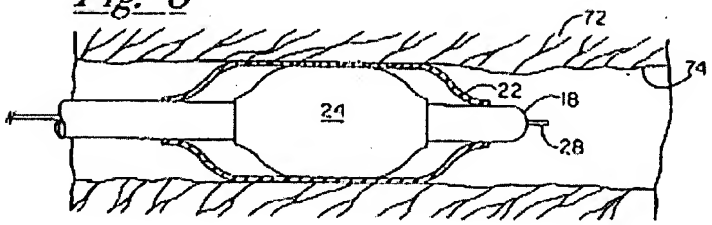


Fig.-6



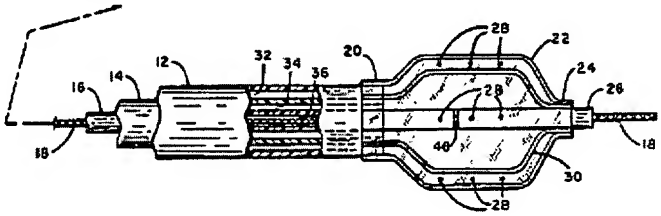
As illustrated in Figures 5 and 6, a catheter 18 has a flexible treatment sheath 22 mounted to a distal end of the catheter and a dilatation balloon 24 within the flexible treatment sheath 22. The flexible treatment sheath 22 is formed of an elastic material, and the dilatation balloon 24 is formed of a substantially inelastic material.

In Figure 5, the catheter 18 has been advanced over a guidewire 28 through vasculature to a treatment site in the vessel (*e.g.*, artery). With the distal region of catheter 18 aligned with a partial occlusion 70 in the vessel as shown, a syringe is used to supply a therapeutic agent under pressure to the compartment 52 (numbered in Fig. 2) between the drug delivery sheath 22 and the balloon 24. The pressurized fluid expands the drug delivery sheath 22 into contact with arterial wall 74 and more specifically with the tissue at partial occlusion 70. As shown in Figure 5, because of the elasticity of sheath 22, the sheath 22 conforms to the shape and contours of the vessel wall. The therapeutic agent perfuses through pores 56 and is applied directly to the arterial tissue wherever sheath 22 and the tissue are contiguous.

Next, as shown in Figure 6, while delivery sheath 22 is maintained in the expanded state, a syringe is used to supply a dilatation fluid to expand the balloon 24. The balloon 24 is substantially inelastic, and, as a result, the balloon 24 when expanded does not conform to the shape and contours of the arterial tissue. Rather, the balloon 24 acts upon the arterial tissue through the sheath 22, compressing the partial occlusion 70 to enlarge the artery as shown in Figure 6.

The Cited References

Shockey discloses a catheter for drug delivery and tissue dilatation, as illustrated below:



The catheter has an inner expander member 30 and an outer expander member or sleeve 22. While the Shockey device has some similarities to Applicant's invention in terms of having inner and outer members, with drug delivery through the outer member, the methods of operation have important and significant differences. In the Applicant's invention there is a two-step process whereby: (1) initially the elastic treatment sheath is expanded into a substantially conforming contact with the surrounding tissue, causing the treatment fluid to pass to the surrounding tissue, while maintaining the dilatation balloon in an unexpanded condition, and (2) thereafter expanding the dilatation balloon for dilatation of the vessel. In Shockey, by contrast, the drug delivery to the tissue and the tissue dilatation are simultaneous. In Shockey, the outer sleeve 22 is not initially expanded to contact the vessel wall for drug delivery to the vessel wall prior to expansion of the inner member 30.

In addition, in the Applicant's invention, the outer treatment sheath is "elastic" and the balloon is "substantially inelastic" for the purpose of enabling the two-step process whereby the outer treatment sheath is initially expanded "into a substantially conforming contact with the surrounding tissue at the treatment site" for drug delivery and the balloon is later separately expanded "to effect a dilatation of the surrounding tissue." Shockey, which does not disclose or even hint at Applicant's two-step process, also does not disclose using different materials for the inner and outer members, much less different materials as claimed in the Applicant's claims. Shockey does not state, suggest or even hint at making the expander member 22 and the inner

sleeve 30 of different materials, much less making the expander member 22 and the inner sleeve 30 of different materials such that the expander member can be fairly characterized as "elastic" in comparison to a substantially inelastic inner sleeve.

Rather than disclose the Applicant's two-step process, Shockey repeatedly emphasizes that its drug delivery and tissue dilatation are simultaneous. Shockey states:

> [An] object of the invention is to provide a dilatation catheter in which the stenotic lesion being treated can be spread and expanded at the same time that it is sprayed with a plaque reducing drug or a substance which forms a stent in situ.

(Col. 2, lines 3-7 (emphasis added).) Shockey further states:

> [A]s the pressure is increased within the innermost sleeve causing it to "balloon" out, the drug is simultaneously forced through the micro-apertures to spray and bathe the lesion being treated with the medicament or substance.

(Col. 2, lines 39-44 (emphasis added).)

Shockey explicitly states that it is only with expansion of the inner sleeve 30 that the device is forced into contact with the vessel wall:

> Once the distal end of the catheter is appropriately positioned with the aid of a radiopaque marker band 46, the selected drug or other material is introduced through the proximal port 40 and through the lumen 32 and into the confines of the outer expander member 22. The injection of the drug will cause some enlargement of the outer expander member 22 but typically the pressure at which the drug material is injected is below the point where substantial amounts of the drug are ejected out through the micropores 28. To perform the simultaneous substance delivery and dilatation, an inflation fluid is next injected through the port 42 and thence through the lumen 34 into the interior of the expander sleeve 30. As the pressure is increased, typically approaching seven to ten atmospheres, the expander member inflates to its predetermined maximum diameter and, in doing so, forces the liquid substance through the ports 28 to effectively spray the lesion being treated with a particular drug or other material. The expansion of the inner sleeve 30 also results in pressure being exerted against the lesion, forcing it against the vessel wall as the drug or other substance is delivered. The combination of the dilatation pressure and the drug substance release will be[en] found to be effective in providing long-term patency to the treated blood vessel.

(Col. 3, line 67-col. 4, line 24 (emphasis added).)

While it is true that in Shockey some minimal insubstantial amount of drug may come out of the micropores 28 before the inner sleeve 30 is expanded, the outer sleeve 22 is not at that time expanded "into a substantially conforming contact with the surrounding tissue at the treatment site" as required by Applicant's claims. There is simply nothing in Shockey which discloses or suggests this.

The Sogard reference does not provide any suggestion or reason for modifying the Shockey procedure such that Shockey's outer sleeve 22 is expanded "into a substantially conforming contact with the surrounding tissue at the treatment site" prior to expansion of the inner sleeve 30. In fact, Sogard is relied upon in the Office Action solely for making the inner sleeve of Shockey of an inelastic material. The Office Action states, "It would have been obvious ... to modify the device of Shockey with a dilatation balloon made of an inelastic material, as taught by Sogard." The Office Action does not say why a person of ordinary skill in the art would choose an "elastic" material for the outer sleeve of Shockey.

More importantly, the Office Action does not even address modifying the Shockey procedure such that Shockey's outer sleeve 22 is expanded "into a substantially conforming contact with the surrounding tissue at the treatment site" prior to expansion of the inner sleeve 30. Such a modification would be contrary to the Shockey disclosure, which explicitly states that its drug delivery from the outer sleeve and vessel dilatation from the inner sleeve should be "simultaneous" and "at the same time" (col. 2, lines 5 & 41; col. 4, lines 8-9). Because Shockey's "simultaneous" process cannot be modified to Applicant's claimed two-step process without destroying the explicit teachings of Shockey, and because such a modification is nowhere suggested by the prior art, the Applicant respectfully requests pre-appeal brief review of, and withdrawal of, the outstanding rejections.

In view of the foregoing, the Applicant respectfully requests favorable reconsideration of this application and allowance of all claims. Should any questions arise, the Examiner is invited to call the undersigned at the number given below. The Commissioner is hereby authorized to charge any fees and credit any overpayments associated with this filing to Kenyon & Kenyon Deposit Account No. 11-0600.

Respectfully submitted,

Dated: May 18, 2009

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